

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 45

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte W. CLARK STILL,
GE LI, and HELMA WENNEMERS

Appeal No. 2003-0998
Application No. 08/676,143

HEARD November 20, 2003

Before WINTERS, MILLS, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 25-33, 35, 36, 39, 42, 43, and 73-75. Claims 68-71 are also pending and have been indicated to be allowable if rewritten in independent form. See Paper No. 36, mailed Nov. 7, 2001, page 9. Claim 25 is representative of the claims on appeal and reads as follows:

25. A library comprising a plurality of distinct synthetic receptors, wherein each synthetic receptor comprises a template covalently linked to two or more oligomers, said template chosen from the group consisting of (a) monocyclic aliphatic hydrocarbons substituted with two or more groups to which oligomers are attached, (b) polycyclic aliphatic hydrocarbons substituted with two

or more groups to which oligomers are attached, and (c) monocyclic heterocycles substituted with two or more groups to which oligomers are attached, said oligomers chosen independently from the group consisting of straight chained, cyclic and branched oligoamide, oligourea, oligourethane, oligosulfonamide, and peptide oligomers, said oligomers comprising three or more monomers, with the proviso that receptors containing only subunits of trimesic acid and 1,2 diaminocyclohexane are excluded.

The examiner relies on the following reference:

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| Lebl et al. (Lebl) | 5,840,485 | Nov. 24, 1998 |
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Claims 25, 31, 36, and 39 stand rejected under 35 U.S.C. § 112, first paragraph, as lacking an adequate written description in the specification.

Claims 25-33, 35, 36, 39, 42, 43, and 73-75 stand rejected under 35 U.S.C. § 112, first paragraph, as nonenabled.

Claims 25-32 and 73 stand rejected under 35 U.S.C. § 102(e) as anticipated by Lebl.

We reverse all of the rejections.

Background

“Receptors are molecules which selectively interact with other molecules.” Specification, page 1. The specification discloses “synthetic receptor(s) which comprises [sic] a polyfunctional organic template covalently linked to two or more oligomers which may independently be the same or different and may independently be straight chain, cyclic or branched.” Page 3.

Discussion

Claim 25 is representative of the subject matter on appeal. Claim 25 is directed to a library comprising synthetic receptors, in which each synthetic receptor comprises a template to which at least two oligomers are attached; the template can be a monocyclic aliphatic hydrocarbon, a polycyclic aliphatic hydrocarbon, or a monocyclic heterocycle, and the oligomers can be oligoamide, oligourea, oligourethane, oligosulfonamide, or peptide oligomers. The claim also requires that each oligomer comprise at least three monomer units, and provides that “receptors containing only subunits of trimesic acid and 1,2 diamino-cyclohexane are excluded” from the scope of the claim.

The examiner rejected the claims as lacking an adequate description, nonenabled, and anticipated by Lebl.

1. Written description

The examiner rejected claims 25, 31, 36, and 39 as containing new matter, on the basis that “[t]he limitation ‘oligomers comprising three or more monomers’ claimed in Claims 25, 31, 36, 39 has no clear support in the specification and the claims as originally filed.” Examiner’s Answer, page 3.

Appellants point to working examples in the specification that comprise oligomers having three monomer units. Appeal Brief, pages 5-6. Appellants argue that even though the claims have been narrowed compared to their original scope, the claims as written are reasonably described in the specification.

“In order to satisfy the written description requirement, the disclosure as originally filed does not have to provide in haec verba support for the claimed subject matter at issue.” Purdue Pharma L.P. v. Faulding, Inc., 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000). Nonetheless, the disclosure must convey with reasonable clarity to those skilled in the art that the inventor was in possession of the invention. See id.

In this case, we agree with Appellants that the specification provides an adequate description of the instant claims. As Appellants point out, the specification provides working examples of synthetic receptors having oligomers composed of three monomer subunits. It is true, as the examiner noted, that the synthetic receptors shown in those examples both comprise polycyclic templates, and therefore do not provide a literal description of receptors comprising three-subunit oligomers and each of the possible templates recited in the claims. However, “[i]t is not necessary that the application describe the claim limitations exactly . . . , but only so clearly that persons of ordinary skill in the art will recognize from the disclosure that appellants invented processes including those limitations.” In re Wertheim, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976).

In this case, the specification adequately describes all of the limitations of the instant claims, even if the specifically disclosed embodiments do not combine all of those limitations in all possible combinations. The disclosure is adequate to show that Appellants were in possession of the invention now claimed at the time the application was filed. The rejection for inadequate written description is reversed.

2. Enablement

The examiner rejected all of the claims on appeal for nonenablement. The examiner acknowledged that the claims were enabled for synthetic receptors having steroids as templates (or the templates recited in claims 68-71) but held that the claims were not enabled for synthetic receptors having monocyclic aliphatic hydrocarbons, polycyclic aliphatic hydrocarbons, or monocyclic heterocycles as templates. See the Examiner's Answer, page 4.

The examiner apparently concluded that the specification was deficient in teaching those skilled in the art both how to make and how to use the claimed products. With regard to how to make the claimed library, the examiner considered several of the Wands factors and concluded that making the claimed products would have required undue experimentation. See the Examiner's Answer, pages 5-6. In addition, the examiner concluded that, even assuming "that one could make synthetic receptor libraries, . . . as encompassed by the present claims, the specification fails to provide sufficient guidance regarding a specific, substantial and credible use for a representative sample of such compounds." Id., pages 6-8.

Appellants argue that the specification exemplifies compounds having a monocyclic heterocycle template, as well as compounds having a polycyclic aliphatic hydrocarbon template. Thus, Appellants assert, "[t]he only template that is not exemplified is a monocyclic aliphatic hydrocarbon. . . . Appellants submit that the person of ordinary skill would expect that a genus including monocyclic

hydrocarbon templates would share the utility of the genus of polycyclic aliphatic hydrocarbons and monocyclic heterocycles.” Appeal Brief, pages 8-9.

As Appellants point out, the initial burden of showing nonenablement is on the examiner. “[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.” In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971), emphasis in original. See also In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993):

[T]he PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement. If the PTO meets this burden, the burden then shifts to the applicant to provide suitable proofs indicating that the specification is indeed enabling.

We agree with Appellants that the examiner has not carried the initial burden of showing that the claims are not enabled by the specification’s disclosure. With regard to making the claimed libraries, the examiner found that:

(1) the claims do not define specific chemical structures for the templates of the recited synthetic receptors;

(2) the working examples in the specification do not show all of the templates encompassed by the claims;

(3) the prior art shows that synthesis of combinatorial libraries often results in products having no utility; and

(4) the claimed invention involves unpredictability because organic synthesis reactions can be unpredictable, and “it is not possible to predict, a priori, the properties of compounds that have not been previously prepared.”

The examiner cited no evidence to support any of these findings. Even assuming for the sake of argument that they are supported by the evidence, however, the examiner has not adequately explained how these findings support a conclusion of nonenablement.

While the broadest claims on appeal are not limited to synthetic receptors having specific, defined templates, the claims nonetheless recite structural requirements for the templates. That is, the templates of the recited receptors must fall within one of the genera of substituted “monocyclic aliphatic hydrocarbons”, substituted “polycyclic aliphatic hydrocarbons” or substituted “monocyclic heterocycles”. Thus, while the claims are not limited to templates defined by chemical formulae, the examiner erred in finding that “the claimed invention is devoid of structural and/or functional constraints regarding the chemical compounds encompassed by the claimed ‘synthetic receptor libraries’.”

Examiner’s Answer, page 5

In addition, while the specification does not exemplify all of the synthetic receptors encompassed by the claimed libraries, the examiner has not disputed Appellants’ contention that the specification exemplifies synthetic receptors having either a monocyclic heterocycle or a polycyclic aliphatic hydrocarbon as a template. See the Examiner’s Answer, pages 13-14. Nor has the examiner provided evidence or sound scientific reasoning to contradict Appellants’ position

that those skilled in the art would expect synthetic receptors having a monocyclic aliphatic template to behave similarly to the exemplified templates.

The examiner's apparent concern with the specification's disclosure is that it does not show all of the templates encompassed by the claims. Such a showing, however, is not required to provide enablement. "It is well settled that patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art." In re Vaeck, 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991). All that is required by § 112 is that the disclosure allow those skilled in the art to practice the claimed invention without undue experimentation.

With regard to using the claimed libraries, the examiner cites the unpredictability of the properties of compounds that have not yet been made, as well as the specification's failure to teach how to use specific compounds that may be made as part of the claimed libraries. See the Examiner's Answer, pages 6-8.

These concerns are not enough to show that undue experimentation would have been required to use the claimed libraries. The specification discloses that the synthetic receptors making up the claimed libraries will have different properties depending on the length and chemical composition of the template and oligomers. See pages 23-29. As a result, combinatorial synthesis produces "a receptor library containing a diverse and numerous number of molecules." Page 29. The specification also discloses assays to identify

members of the claimed libraries that have a particular biological activity. See, e.g., pages 17-21.

The specification also provides working examples of receptor libraries containing synthetic receptors that bind the neuropeptides Leu Enkephalin and Met Enkephalin. See pages 72-81. Based on the results of these examples, the specification concludes that “the methods described [in the specification] may allow the development of receptors for almost any substrates even without knowing the exact shape, size and arrangement of functionalities involved.”

Page 82.

The examiner has not provided adequate evidence or sound scientific reasoning to support a conclusion to the contrary. Thus, the examiner has not shown that undue experimentation would have been required either to make or to use the claimed synthetic receptor libraries. The rejection for nonenablement is reversed.

3. Anticipation

The examiner rejected claims 25-32 and 73 as anticipated by Lebl. The examiner characterized Lebl as disclosing “libraries of synthetic test compounds” comprising compounds meeting the “template” and “oligomer” limitations of the instant claims; the examiner points specifically to Lebl’s compounds 2-5, 7, 11, 12, 14, and 15 as meeting the limitations of the instant claims. See the Examiner’s Answer, pages 8-10.

Appellants acknowledge that Lebl’s “Example 11 comes the closest to providing a cyclic scaffold with the possibility for attaching more than one

oligomer,” but argue that that example at best discloses compounds having two-subunit oligomers. Since the claims on appeal require oligomers having at least three monomer units, Appellants conclude, “[n]one of the scaffold/subunit combinations described by Lebl falls within Appellants’ pending claims.” Appeal Brief, pages 13-14.

“Under 35 U.S.C. § 102, every limitation of a claim must identically appear in a single prior art reference for it to anticipate the claim.” Gechter v. Davidson, 116 F.3d 1454, 1457, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997). “Every element of the claimed invention must be literally present, arranged as in the claim.” Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

We agree with Appellants that the examiner has not shown that Lebl discloses a library meeting all the limitations of the instant claims. At best, the examiner has pointed to general disclosures in the reference that might encompass compounds having one of the templates recited in the claims and that could have oligomers made up of at least three monomers of the recited subunits. See, e.g., the Examiner’s Answer, pages 15-17. The examiner has not, however, pointed to a specific compound that meets the limitations of a “synthetic receptor” recited in claim 25, much less a library comprising a plurality of such synthetic receptors. Therefore, the examiner has not shown that Lebl anticipates the instant claims. The rejection under 35 U.S.C. § 102(e) is reversed.

Summary

The rejections for lack of written description, nonenablement, and anticipation are not supported by the evidence of record and are therefore reversed.

REVERSED

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| Sherman D. Winters |) | |
| Administrative Patent Judge |) | |
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| |) | BOARD OF PATENT |
| Demetra J. Mills |) | |
| Administrative Patent Judge |) | APPEALS AND |
| |) | |
| |) | INTERFERENCES |
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